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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,520	12/04/2000	Ana Rodriguez	GC647	4557

5100 7590 11/21/2003

GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
925 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER	
EPPERSON, JON D	

ART UNIT	PAPER NUMBER
1639	16

DATE MAILED: 11/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
File Copy	09/729,520	RODRIGUEZ ET AL.	
	Examin r	Art Unit	
	Jon D Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

1. The Response filed August 19, 2003 (Paper No. 15) is acknowledged.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Claims

3. Claims 1-7 were pending. Claim 1 was amended, claim 7 was cancelled and claim 8 was added. Therefore, claims 1-6 and 8 are currently pending and examined on the merits.

Withdrawn Objections/Rejections

4. All outstanding rejections and/or objections are withdrawn in view of Applicants' amendments and/or arguments.

New Rejections

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1-6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Weidenhammer et al (U.S. Patent No. 6,379,897) (Filing Date is ***November 9, 2000***).

For ***claim 1***, Weidenhammer et al (see entire document) discloses methods for preparing a library of mutant nucleic acids (see Weidenhammer et al, abstract; see also column 1, paragraph, 1), which anticipates claim 1. For example, Weidenhammer et al discloses, **[a]** "obtaining a template nucleic acid" from biological samples (e.g., see Weidenhammer et al, column 3, lines 35-54, "sequence of interest are amplified from a fixed amount of template generated from the reverse transcription of the mRNA population isolated from the biological sample"; see also column 7, lines 45-62; see also column 8, paragraphs 2-3; see also Examples). In addition, Weidenhammer et al discloses **[b-d]** preparing a first and second oligonucleotide corresponding to a first and second desired mutation within said template nucleic acid and allowing them to hybridize to a template (e.g., see Weidenhammer et al, column 8, last paragraph wherein "chimeric oligonucleotide(s)" are used as primers for the library; see also column 10, lines 49-60, "The chimeric oligonucleotide will then be designed to generate the desired restriction endonuclease recognition site by altering the target sequence during primer extension. Such alterations may include changing, inserting or deleting nucleotides as necessary to

generate type IIs restriction endonuclease recognition site into the amplified target"; see also column 11, paragraph 1, lines 5-7, "mutated oligonucleotide sequence [i.e., primer]"; see also column 9, last paragraph wherein the primers may be a mixture of random short polynucleotides e.g., random hexamer primers; see also column 9, paragraph 2; see especially claims 16, 19). Finally, Weidenhammer et al discloses **[e]** subjecting the mixture of primers to linear cyclic amplification to produce a library of mutant template nucleic acids (e.g., see Weidenhammer et al, column 8, last paragraph, especially lines 44-46, "Following cDNA synthesis, the target(s) of interest may be linearly amplified by primer extension of a chimeric oligonucleotide(s) using DNA polymerase. Linear amplification either by primer extension, as here, or by other means (such as in vitro transcription, used below), is necessary in order to allow quantitative comparison between different samples").

For ***claim 2, 4 and 8***, Weidenhammer et al discloses that the primers can be completely random and thus would include discontiguous primers and also that the primers can bind to different mRNAs or different cDNAs which would also be discontiguous (e.g., see column 9, last paragraph; see also column 8, last paragraph, see also column 9, paragraph 2, "The sets of chimeric oligonucleotides that are used in target preparation will generally represent at least two distinct target species but may represent 10, 20, 40, or even up to 50 distinct target species"; see also claim 19).

In addition, Weidenhammer et al discloses that both mutant and non-mutant oligonucleotides can be used (e.g., see Weidenhammer et al, column 10, last three paragraphs disclosing both "mutant" and "non-mutant" chimeric primers that bind to

targets that either contain class IIs sequences or do not contain class IIs sequences, respectively).

For ***claim 3***, Weidenhammer et al discloses oligonucleotides that are present in less than saturating conditions (e.g., see Weidenhammer et al, figure 5a; see also Examples).

For ***claim 5***, Weidenhammer et al discloses that the "target" nucleic acids refer to a "gene" of interest (see column 7, line 11). A "gene" is a DNA segment that encodes (i.e., "corresponds") a protein and, as a result, claim 5 is anticipated (see column 7, lines 6-11).

For ***claim 6***, Weidenhammer et al discloses that the target protein can be any target that is expressed in cells including IL1, TGFβ2, IL6, etc (e.g., see column 21, paragraph 1).

6. Claims 1-6 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Caldwell et al (U.S. Patent No. 6,582,914) (Filing Date is ***October 26, 2000***).

For ***claim 1***, Caldwell et al (see entire document) discloses methods for generating a library of oligonucleotides comprising a controlled distribution of mutations (see Caldwell et al, abstract), which anticipates claim 1. For example, Caldwell et al discloses, **[a]** "obtaining a template nucleic acid" (e.g., see Caldwell et al, claim 1, step (a)). In addition, Caldwell et al discloses **[b-d]** preparing a first and second oligonucleotide corresponding to a first and second desired mutation within said template

nucleic acid and allowing them to hybridize to a template (e.g., see Caldwell et al, claim 1, step (c); see also figures 1-2; see also Summary of the Invention). Furthermore, Caldwell et al discloses that the first and second oligonucleotide can be non-complementary (e.g., see Caldwell et al, figures 1-2 showing non-complementary primers; see also Summary of invention). Finally, Caldwell et al discloses **[e]** subjecting the mixture of primers to linear cyclic amplification to produce a library of mutant template nucleic acids (e.g., see Caldwell et al, column 11, lines 25-26, "long products increases linearly because they are produce only from the original nucleic acid"; see also claim 1; see also Summary of Invention).

For ***claim 2,*** Caldwell et al discloses that oligonucleotides in said steps (b) and (c) are discontiguous (e.g., see Caldwell et al, lines 26-31; see also figures 1-2; see also Summary of Invention).

For ***claim 3***, Caldwell et al discloses oligonucleotides that are present in less than saturating conditions (e.g., see Caldwell et al, claim 1, step (e)).

For ***claim 4***, Caldwell et al further discloses non-mutagenic primers (e.g., see Caldwell et al, abstract).

For ***claims 5-6***, Caldwell et al discloses protein products selected from an enzyme, hormone, vaccine, antibody, etc. (e.g., see Caldwell et al, claim 5).

For ***claim 8***, Caldwell et al discloses more than two said non-mutagenic primers (e.g., see Caldwell et al, abstract, see also figures 1-2, see also column 7, paragraph 2).

Conclusion

Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D. Epperson, Ph.D. whose telephone number is (703) 308-2423. The examiner can normally be reached on Monday-Thursday from 9:30 to 7:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Jon D. Epperson, Ph.D.
November 8, 2003

BENNETT CELSA
PRIMARY EXAMINER